IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

ZELDA GUNTER AND LONNIE GUNTER,	)	
Plaintiff,	)	
v.	)	**C.A. No.: N20C-11-032 PEL**
BOSTON SCIENTIFIC CORPORATION,	)	
Defendants.	)	

Submitted: January 22, 2021
Decided: May 12, 2021

ON DEFENDANT'S MOTION TO DISMISS
DENIED in part / GRANTED in part

OPINION AND ORDER

Robert J. Leoni, Esquire, Shelby & Leoni, 221 Main Street Wilmington, DE 19804, Attorneys for Plaintiff.

Colleen Shields, Esquire and Alexandra D. Rogin, Esquire Eckert, Seamans, Cherin & Mellott LLC, 221 Main Street, Stanton, DE 19804, Attorneys for Defendant

Jones, J.

Plaintiff Zelda Gunter has brought suit against the Defendant, Boston Scientific Corporation ("Boston Scientific"), alleging numerous claims sounding in strict liability, negligence, and breach of various warranties arising out of personal injuries she claims to have suffered from a mesh device that was surgically implanted within her. Zelda alleges that Boston Scientific defectively designed and manufactured the mesh device in question, which is called the "Advantage Fit." Lonnie Gunter has brought a derivative loss of consortium claim based on Zelda's injuries.

The Defendant has moved to dismiss the complaint on the following grounds: (1) Plaintiffs failure to warn claims are barred by the learned intermediary doctrine and fail to adequately allege how the Advantage Fit proximately caused the alleged injuries; (2) Plaintiffs' negligence claims based on negligent manufacturing and/or design are barred by Comment *k* of Section 402A of the Restatement (Second) of Torts, and lack sufficient allegations of proximate cause; (3) Plaintiffs' breach of warranty claims do not identify any affirmation or promise from Boston Scientific that Ms. Gunter received and reasonably relied upon; and (4) Plaintiff's request for punitive damages should be stricken because they have not alleged sufficient facts to support damages under Alabama law.

For the reasons set forth below Boston Scientific's Motion to Dismiss is **granted in part** and **denied in part.**

BACKGROUND

The background of this case is taken from the factual allegations set forth in Plaintiffs' complaint, which this Court must accept as true in deciding the motion to dismiss.

Zelda Gunter is a 58-year old woman who resides in Anniston, Alabama and is married to Lonnie Gunter. On February 2, 2018, Mrs. Gunter underwent surgical implantation of Defendant's Advantage Fit pelvic mesh device at Northeastern Alabama Regional Medical Center in Anniston, Alabama. On November 5, 2018, Mrs. Gunter underwent revision surgery to remove mesh from the Advantage Fit device that had inhibited her ability to urinate. As a result of the implantation of the Advantage Fit, Plaintiff has suffered pain, erosion, urinary problems, dyspareunia, organ perforation, and vaginal scarring related to complications from Defendant's mesh product. Plaintiffs filed suit on November 4, 2020.

STANDARD OF REVIEW

Under Superior Court Rule 12(b)(6), the Court may dismiss a claim for failure to state a claim upon which relief can be granted only where the plaintiff cannot recover under any reasonable conceivable set of circumstances or facts susceptible of proof that may be inferred from the allegations. The Court accepts the well-pled allegations of the complaint as true and draws all reasonable inferences that logically

flow from those allegations in favor of the non-moving party.[1] Under Delaware law, in order to survive a motion to dismiss for failure to state a claim, a complaint need only give general notice of the claim asserted, and a claim will not be dismissed unless it is clearly without merit, either as a matter of law or fact.[2] A Court can dismiss for failure to state a claim on which relief can be granted only if it appears with reasonable certainty that the plaintiff could not prove any set of facts that would entitle her to relief.[3]

Under *Del. Super. Ct. Civ.* Rule 9(b) a plaintiff must plead negligence with particularity. The purpose of Rule 9(b) is to apprise the adversary of the acts or omissions by which it is alleged that a duty has been violated so that an opponent is able to prepare a defense to them.[4] Under Rule 9(b) it is usually necessary to allege only sufficient facts out of which a duty is implied and a general averment of failure to discharge that duty.[5]

FAILURE TO WARN CLAIMS

Defendant first alleges that plaintiffs' claims premised on an alleged failure to warn should be dismissed under the learned intermediary doctrine.

---

[1] *Tanesha Maretta Williams v. Newark Country Club*, 2016 WL 6781221 at *1 (Del.Super., November 2, 2016); *William L. Spence Jr., v. Allison J. Funk, et al.,* 396 A.2d 967, 968 (Del. 1978); *Richard Clinton, et al. v. Enterprise Rent-a-Car Co., et al.,* 977 A.2d 892, 895 (Del. 2009).
[2] *Wilen v. Pollution Control Industries,* Inc., Del. Ch. C.A. No 7254-NC (Consolidate). Harnett, V.C. (Oct 15, 2984).
[3] *Rammuno v. Cawley*, 705 A 2d 1029, 1034 (Del 1998).
[4] *Chesapeake & Potomac Tel. Co. of Maryland v. Chesapeake Utilities Corp.*, 436 A.2d 314, 338 (Del 1981).
[5] *State Farm Fire & Cas., Co v. Gen. Elec. Co.*, 2009 WL 5177156 (Del. Super., 2009).

Alabama has adopted the learned intermediary doctrine, under which a medical device manufacturer owes a duty to warn only a prescribing physician, not the patient.[6] The doctrine has been described as follows:

> "[I]n Alabama, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product. The adequacy of the manufacturer's warning is measured by its effect on the physician, [ ] to whom it owed a duty to warn, and not by its effect on the consumer. . . .In such a situation [where the patient alleges inadequate warnings] the patient must show that: [T]he manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury. In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient." *Tutwiler v. Sandoz, Inc.*, 726 Fed. Appx. 724 (11th Cir. 2018)(citations and quotations omitted.)

In response to Defendant's argument, Plaintiffs point to the following paragraphs of the Complaint:

- The Defendant has consistently underreported and withheld information about propensity of Defendant's Pelvic mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large. (¶9)

- Defendant has known and continue to know that some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate Device; that there were and are differences between the Defendant's Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that

[6] *Morguson v. 3M Co.*, 857 s.2d 796, (Ala. 2003).

> significant differences exist and exited between the Pelvic Mesh Products and their predecessors and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed information and failed to accurately and completely disseminate or share this and or critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh products and the procedure for implantation was and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh products into the Plaintiff. (¶12)
>
> - **Causation**: After, and as a result of the implantation of the Medical Devises, Plaintiff Izabella Shealy suffered serious bodily injuries, including, but not limited to erosion and other injuries similar to the ones described in the FDA's Public Health Advisory of October 20, 2008. (¶48)
> - **Causation**: These injuries would not have occurred but for the defective nature of the products implanted and/or Defendant's wrongful conduct. (¶49)
> - As a result of having the Medical Devise implanted into her, Izabella Shealy has experienced significant mental and physical pain and suffering, and she has sustained permanent injury. (¶50)

At this stage of the proceedings, the above allegations lead this Court to conclude that the Plaintiff has sufficiently pled a failure to warn claim. The claim clearly indicates that the Defendant mislead the medical community and the injuries described in the complaint would not have occurred but for the Defendant's wrongful conduct. While the Complaint could have been better drafted by containing a specific allegation that the implanting doctor would not have implanted

the device at issue had a proper warning been given, paragraphs 9 and 49 are sufficient (although barely), at this stage of the proceedings to withstand a motion to dismiss on the learned intermediary doctrine and the proximate cause requirements that follow from that doctrine. At the motion to dismiss stage, the complaint has articulated a reasonable set of facts (and the inferences flowing from those facts) which could make the Defendant liable for failure to warn.

COMMENT K of SECTION 402A

Boston Scientific argues that Plaintiffs manufacturing and design defect claims fail because Alabama has adopted Comment *k* of Section 402 of the Restatement (Second) of Torts. Under this Section, traditional manufacturing or design defect claims in cases involving "unavoidably unsafe" medical products are precluded. Comment *k* of Section 402 precludes manufacturing or design defect claims based on either a strict liability or negligence theory.[7] One Court has described this legal principle as follows:

> Alabama's adoption of comment *k* of the Restatement (Second) of Torts limits design defect claims involving "unavoidably unsafe product such as prescription drugs. *See Stone*, 447 So. 2d at 1303 n.1; *see also* Restatement (Second) of Torts § 402A cmt. k (1965). Alabama recognizes that some products, despite their utility, are quite incapable of being made safe for their intended and ordinary use. *Stone*, 447 So. 2d at 1303 n.1. In *Stone*, the Court held that prescription drugs reside in this category of products. *Id.* at 1303-4. Indeed, in the case of 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous. *Id.* at 1304.

[7] *McDaniel v. Mylan, Inc.* 2019 WL 11638407 (U.S.D.C. N.D.Ala. 2019).

> Thus, 'no AEMLD design defect claim for prescription drugs exists apart from a challenge to the adequacy of the warning." *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709-MHH, 2016 WL 1086028 at *3 (N.D. Ala. Mar. 21 2016); *see also Stone*, 447 So. 2d at 1304 ("[T]he issue of adequate warning pertains to the initial establishment of liability rather than constituting some type of affirmative defense.")…
>
> Comment *k* also applies to Plaintiff's negligence claim. Although AEMLD claims and common law negligence claims 'have different elements that must be proven… there is nevertheless a measure of commonality between those claims." *McMahon*, 95 So. 3d at 772. Indeed, under both theories, Plaintiff must show that "the product at issue is defective." *See* Restatement (Second) of Torts § 402A cmt. *k* (1965) (stating that an unavoidably unsafe product 'accompanied by proper directions and warnings is *not defective*" (emphasis added)). Therefore, Alabama's adoption of comment *k*'s must apply equally to both negligence and AEMLD claims. *See Barcal*, 2016 WL 1086028, at *3 (dismissing a negligence claim based on a drug's defective design because comment *k's* rationale is "equally applicable" to negligence claims".)

Plaintiffs take issue with Boston Scientific's position arguing that Comment *k* has not been adopted by any state court in Alabama and is therefore not the law in Alabama. Plaintiffs are incorrect. *Purvis v. PPG Industries, Inc.* 502 So.2d 714 (1987) involved a dry cleaning product called perchloroethylene. The Alabama Supreme Court in *Purvis* specifically held that Comment *k* applied to the dry cleaning product. The Court wrote:

> Perc is an unavoidably unsafe product. In *Stone v. Smith, Kline & French Laboratories*, 447 So.2d 1301 (Ala.1984), this Court, adopting comment k to Section 402A of the *Restatement (Second) of Torts*, (1965) at an unavoidably unsafe product, when properly prepared and accompanied by proper directions

> and warnings, is not "defective" or "unreasonably dangerous" under Alabama's Extended Manufacturer's Liability Doctrine.[8]
>
> The *Stone* case involved the drug Thorazine. Comment k to Section 402A has most often been applied in drug cases; however, it has also been applied in cases involving other products: *Racer v. Utterman,* 629 S.W.2d 387 (Mo.App.1981) (a surgical drape), appeal dismissed, cert. denied, *Racer v. Johnson & Johnson,* 459 U.S. 803, 103 S.Ct. 26, 74 L.Ed.2d 42 (1982); *Daniels v. Combustion Engineering, Inc.,* 583 S.W.2d 768 (Tenn.App.1978) (asbestos installation); *McMichael v. American Red Cross,* 532 S.W.2d 7 (Ky.1979) (blood); *McKee v. Moore,* 648 P.2d 21 (Okla.1981) (intrauterine device).
>
> Because there are many similarities between this case and these other Section 402A, comment k cases, it seems reasonable to extend comment k to an effective dry cleaning solvent such as perc. Each involves the distribution of a product that, no matter how carefully manufactured or used, can conceivably cause physical injury. Each involves a commercial situation in which the identity of the ultimate user of the product is unknown to the manufacturer. Each involves a professional "middleman" between the manufacturer and the ultimate user, a middleman who is by training, experience, and instruction familiar with the risks inherent in the use of the product. And each involves a manufacturer who has extended adequate warnings regarding product risks to the middleman.

At least one other Court has held that Comment *k* applies to medical devices, as opposed to prescription drugs.[9] This Court finds that Comment *k* is reflects the law in Alabama and applies to Defendant's pelvic mesh device. Plaintiff's claims

[8] Comment k reads as follows:
"Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. ... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. ... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

[9] *Emody v. Medtronic, Inc.*, 238 F. Supp.2d 1291 (N.D.Ala 2003).

for design and/or manufacturing defect are dismissed and the Defendant's motion is **GRANTED** for these claims. To be clear, Comment *k* has no applicability to plaintiffs' failure to warn claims – those claims survive.

IMPLIED WARRANTY CLAIMS

Boston Scientific claims that Plaintiffs have failed to state a claim for breach of the implied warrant of merchantability and the implied warranty of fitness for a particular purpose. Boston Scientific is incorrect with respect to the former, and correct with respect to the latter.

The implied warranty of merchantability is found in §7-2-314 Ala. Code 1975 which provides:

> Ala.Code 1975 § 7-2-314
>
> §7-2-314. Implied warranty: Merchantability; usage of trade; human blood and tissues.
>
> (1) Unless excluded or modified (Section 7-2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.

Subsection 2(c) of that Code section provides that to be considered merchantable, goods must be "fit for the ordinary purposes for which such goods are used." As the Court of Civil Appeals held, "[t]o establish his claim for breach of the implied warranty of merchantability, plaintiffs [must] prove the existence of the implied warrant, a breach of that warrant, and damages proximately resulting from that breach" *Tucker v. General Motors*, 769 So.2d at 901 (Ala.Civ.Appl. 1998)

(quoting *Barrington Corp. v. Patrick Lumber Co.*, 447 So.2d 785, 787 (Ala.Civ.Appl. 1984) (internal quotations omitted).

Plaintiff's complaint alleges that Boston Scientific designed, manufactured, marketed, packaged and labeled the Advantage Fit device implanted in Mrs. Gunter.[10] The complaint specifies the defects in the Advantage Fit, including that it did not "perform as intended" due to its utilization of polypropylene mesh, the placement of the mesh transvaginally, and due to the Advantage Fit's incompatibility with the biomechanics of the vagina.[11] There is no dispute that the Advantage Fit was sold and implanted in the manner foreseen by Defendant.[12] Finally, Plaintiffs clearly alleged in their complaint that the Boston Scientific Advantage Fit device was the cause of their injuries.[13] Plaintiffs have sufficiently pled a claim for breach of the implied warrant of merchantability, and the Defendant's Motion to Dismiss is **denied** on this point.

Plaintiffs have not challenged in any way Boston Specific's arguments regarding their claim based on an implied warranty of fitness. In the absence of any challenge on this point, the Defendant's Motion is **GRANTED** and Plaintiff's claims based on the implied warranty are **DISMISSED**.

[10] *See Exhibit A at para 5*.
[11] *Id.* at paras 6-8.
[12] *Id.* at paras 46-47.
[13] *Id*. at paras 48-50.

EXPRESS WARRANTIES

Boston Scientific next moves to dismiss Plaintiffs' claim for breach of express warranty. To maintain a breach of express warranty claim, Plaintiff must prove the existence of an express warranty, breach of the warranty and proximate causation of damages.[14] Under Alabama law, the crux of all express warranty claims is that the goods did not conform to the warranty.[15] Boston Scientific claims that Plaintiffs do not allege that Mrs. Gunter received an affirmation or promise from the company concerning the Advantage Fit's performance. She therefore could not have actually relied on an affirmation or promise from Boston Scientific.

In response, Plaintiff relies upon the allegations in paragraphs 5, 8, 12, 23-24 and 48-50 of the complaint as support for a properly pled breach of express warranty. This Court's review of these paragraphs leads it to conclude that the Plaintiff has properly pled an express warranty claim.[16]

PUNITIVE DAMAGES

Defendant claims "[T]here are absolutely no facts from which the trier of fact could plausibly infer that Boston Scientific had knowledge that its alleged actions or failures to act would make Plaintiff's alleged injuries likely or probable, as opposed to merely possible." To be entitled to punitive damages, Alabama law requires

[14] *Clark v. Allied Healthcare prods., Inc.*, 601 So.2d 902 (Ala. 1992).
[15] *Ex parte Miller*, 693 So.2d 1372, 1376 (Ala. 1997).
[16] Boston Scientific further maintains that the express warranty claim fails because Plaintiffs did not give the mandatory pre-suit notice required by Ala. Code §7-2-607(3)(1). As this is a personal injury claim, no mandatory notice is required. *Hobbs v. GMC*, 134 F.Supp.2d 1277, 1285-86 (M.D. Ala.2001).

showing of "wantonness" on the part of a defendant, which is defined as "conduct which is carried on with a reckless or conscious disregard of the right and safety of others".[17]

Plaintiffs' complaint alleged the following:

> - Despite emerging scientific evidence that polypropylene is incompatible with human tissue, Defendant continues to market the Fit to the medical community. *See* ¶¶ 5-6.
> - Contrary to the Defendant's representations and marketing…the Defendant's products suffer from high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe reversible injuries. *Id.* ¶ 8.
> - The Defendant has chronically underreported and withheld information about the propensity of Defendant's Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large. ¶¶ 9-10.
> - Defendant "failed to accurately and completely inform the FDA, health providers and patients." *Id.* at para 11.
> - Defendants continue to mislead the public into believing their products are safe and effective. *Id.*

In this Court's view these allegations sufficiently plead wantonness on the part of Boston Scientific, and adequately state a claim for punitive damages under Alabama law.

[17] *Ala. Code* §6.11.20(b)(3).

LOSS OF CONSORTIUM

Defendant asserts that Lonnie Gunter's Loss of Consortium claim fails as a matter of law and must be dismissed because it is a derivative claim based on Zelda's direct claims in this litigation. Defendant argues that since all of the Plaintiffs' direct claims fail, the derivative loss of consortium claim must be dismissed. Because at least some of the underlying direct claims survive as a matter of law, Plaintiffs' derivative loss of consortium claim also survives at this stage.

IT IS SO ORDERED.

/S/ Francis J. Jones, Jr.
Francis J. Jones, Jr., Judge

cc: File&ServeXpress